

4-13-04



Attorney Docket No. VPI/99-100DIV2

Applicants : Michael R. Hale, et al.  
Application No. : 10/613,650 Confirmation No.: 4616  
Filed : July 2, 2003  
For : INHIBITORS OF ASPARTYL PROTEASE  
Group Art Unit : 1614  
Examiner : Not yet assigned

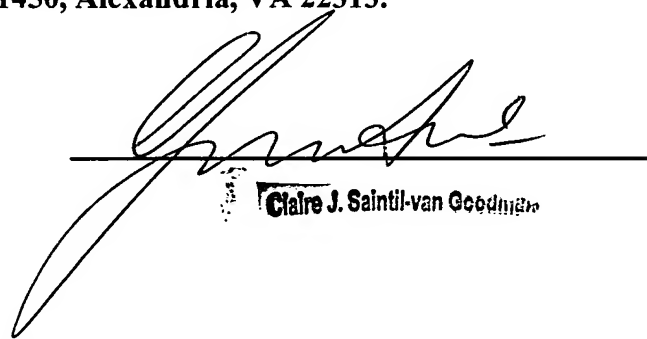
New York, New York 10020  
April 12, 2004

Hon. Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

“Express Mail” mailing label number EV132198523US

Date of Deposit April 12, 2004

I hereby certify that this paper/fee is being deposited with the United States Postal Service “EXPRESS MAIL POST OFFICE TO ADDRESSEE” service under 37 C.F.R. 1.10 on the date indicated above and is addressed to the Hon. Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313.



Claire J. Saintil-van Gooch

**Encl:**

- Transmittal Letter (in duplicate);
- Information Disclosure Statement (in duplicate);
- Form PTO-1449 (in duplicate)



VPI/99-100DIV2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner : Not Yet Assigned  
Group : 1614  
Applicants : Michael R. Hale, et al.  
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New York, New York  
April 12, 2004

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P.O. Box 1450  
Alexandria, Virginia 22313-1450

TRANSMITTAL LETTER FOR  
INFORMATION DISCLOSURE STATEMENT

Sir:

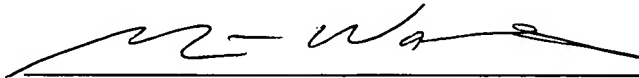
Transmitted herewith is an Information Disclosure Statement in the above-identified application. This Statement is submitted:

- ☐ [ ] within three months of the application filing date;
- ☒ [x] more than three months from the application filing date but before the mailing date of the first Office Action on the merits.

In accordance with 37 C.F.R. §§ 1.97(b)(3), submission of this Statement requires no fee. However, if for any reason a fee is due, the Director is hereby authorized to charge payment of any fees required in

connection with this Information Disclosure Statement to  
Deposit Account No. 06-1075. A duplicate copy of this  
letter is transmitted herewith.

Respectfully submitted,



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James F. Haley, Jr. (Reg. No. 27,794)  
Min Wang (Reg. No. 51,303)  
Attorneys for Applicants

c/o FISH & NEAVE  
Customer No. 1473  
1251 Avenue of the Americas  
New York, New York 10020-1104  
Tel.: (212) 596-9000



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Alexandria, Virginia 22313-1450

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §§ 1.56 and 1.97,  
applicants, through their representatives, make of record  
the following documents:\*

UNITED STATES PATENTS

| <u>Inventor</u> | <u>Patent No.</u> | <u>Issue Date</u> |
|-----------------|-------------------|-------------------|
| Ryono et al.    | 4,629,724         | December 16, 1986 |
| Tung et al.     | 5,723,490         | March 3, 1998     |
| Vasquez et al.  | 5,843,946         | December 1, 1998  |

\* For the convenience of the Examiner, a completed Form PTO-1449 listing these documents, is attached. Copies of all the documents listed herein were submitted by applicants in the grandparent United States Patent Application No. 09/500,781, now United States Patent 6,319,946; or were cited by the Examiner during prosecution of the parent United States Patent Application No. 09/927,271, now United States Patent 6,617,350. Pursuant to 37 C.F.R. §1.98(d), applicants have not enclosed copies of the listed documents. However, applicants stand ready to provide copies at the Examiner's request.

EV132198523US

#### FOREIGN PATENTS

| <u>Country</u> | <u>Patent No.</u> | <u>Publication Date</u> |
|----------------|-------------------|-------------------------|
| EPO            | EP 0159156A1      | October 23, 1985        |
| EPO            | EP 0594540A1      | April 27, 1994          |
| PCT            | WO 94/04492       | March 3, 1994           |
| PCT            | WO 94/05639       | March 17, 1994          |
| PCT            | WO 94/10136       | May 11, 1994            |
| PCT            | WO 95/06030       | March 2, 1995           |
| PCT            | WO 95/07269       | March 16, 1995          |
| PCT            | WO 95/09843       | April 13, 1995          |
| PCT            | WO 95/14016       | May 26, 1995            |
| PCT            | WO 95/32185       | November 30, 1995       |
| PCT            | WO 96/33187       | October 24, 1996        |

#### OTHER DOCUMENTS

A.K. Ghosh et al., "Potent HIV Protease Inhibitors Incorporating High-Affinity P<sub>2</sub>-Ligands and (R)-(Hydroxyethylamino)sulfonamide Isostere," Bioorg. Med. Chem. Lett., 8, pp. 687-690 (1998).

S. J. Hays et al., "Synthesis of cis-4-(Phosphonoxy)-2-piperidinecarboxylic Acid, an N-Methyl-D-aspartate Antagonist," J. Org. Chem., 56, pp. 4084-4086 (1991).

Y. Kiso et al., "'O→N Intramolecular Acyl Migration'-type Prodrugs of Tripeptide Inhibitors of HIV Protease," Peptides: Chemistry, Structure and Biology, 61, pp. 157-159 (1996).

A.C. Nair et al., "A Computational Study of the Resistance of HIV-1 Aspartic Protease to the Inhibitors ABT-538 and VX-478 and Design of New Analogues," Biochem. Biophys. Res. Commun., 242, pp. 545-551 (1998).

J.W. Perich et al., "The Synthesis of Multiple O-Phosphoseryl-Containing Peptides via Phenyl Phosphate Protection," J. Org. Chem., 53, pp. 4103-4105 (1988).

M.S. Plummer et al., "Design of Peptidomimetic Ligands for the pp60<sup>src</sup> SH2 Domain," Bioorganic & Medicinal Chemistry, 5, pp. 41-47 (1997).

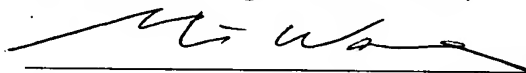
S. Yamaguchi et al., "Synthesis of HIV Protease Dipeptide Inhibitors and Prodrugs," Peptide Chemistry 1996, pp. 297-300 (1997).

Banker et al., Modern Pharmaceutics, pp. 627-629 (1996).

C.T. Baker et al., "Design, Synthesis and Conformational Analysis of A Novel Series of HIV Protease Inhibitors," Bioorg. & Med. Chem. Lett., vol. 8, pp. 3631-3636 (1998).

Applicants respectfully request that the above-cited documents be (1) fully considered by the Examiner during the course of the examination of this application and (2) printed on any patent issuing from this application. Applicants also request that a copy of the enclosed Form PTO-1449 duly initialed by the Examiner be forwarded to the undersigned with the next communication.

Respectfully submitted,



James F. Haley, Jr. (Reg. No. 27,794)

Min Wang (Reg. No. 51,303)

Attorneys for Applicants

c/o FISH & NEAVE

Customer No. 1473

1251 Avenue of the Americas

50th Floor

New York, New York 10020-1104

Tel: (212) 596-9000

FORM PTO-1449

U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.  
VPI/99-100DIV2APPLICATION  
NO.: 10/613,650INFORMATION DISCLOSURE  
STATEMENT BY APPLICANTAPPLICANTS  
Michael R. Hale, et al.CONFIRMATION NO.:  
4616FILING DATE  
July 2, 2003GROUP  
1614

## U.S. PATENT DOCUMENTS

| EXAMINER<br>INITIAL | DOCUMENT<br>NUMBER | DATE     | NAME           | CLASS | SUBCLASS | FILING DATE<br>IF<br>APPROPRIATE |
|---------------------|--------------------|----------|----------------|-------|----------|----------------------------------|
|                     | 4,629,724          | 12/16/86 | Ryono et al.   |       |          |                                  |
|                     | 5,843,946          | 12/1/98  | Vasquez et al. |       |          |                                  |
|                     | 5,723,490          | 3/3/98   | Tung           |       |          |                                  |
|                     |                    |          |                |       |          |                                  |
|                     |                    |          |                |       |          |                                  |
|                     |                    |          |                |       |          |                                  |
|                     |                    |          |                |       |          |                                  |

## FOREIGN PATENT DOCUMENTS

| EXAMINER<br>INITIAL | DOCUMENT<br>NUMBER | DATE     | COUNTRY | CLASS | SUBCLASS | TRANSLATION |    |
|---------------------|--------------------|----------|---------|-------|----------|-------------|----|
|                     |                    |          |         |       |          | YES         | NO |
|                     | 0 159 156          | 10/23/85 | EP      |       |          |             |    |
|                     | 0 594 540 A1       | 4/27/94  | EP      |       |          |             |    |
|                     | WO94/04492         | 3/3/94   | PCT     |       |          |             |    |
|                     | WO94/05639         | 3/17/94  | PCT     |       |          |             |    |
|                     | WO94/10136         | 5/11/94  | PCT     |       |          |             |    |
|                     | WO95/06030         | 3/2/95   | PCT     |       |          |             |    |
|                     | WO95/07269         | 3/16/95  | PCT     |       |          |             |    |
|                     | WO95/09843         | 4/13/95  | PCT     |       |          |             |    |
|                     | WO95/14016         | 5/26/95  | PCT     |       |          |             |    |
|                     | WO95/32185         | 11/30/95 | PCT     |       |          |             |    |
|                     | WO96/33187         | 10/24/96 | PCT     |       |          |             |    |
|                     |                    |          |         |       |          |             |    |
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|                     |                    |          |         |       |          |             |    |

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not conformance and not considered. Include copy of this form with next communication to applicant.

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FORM PTO-1449

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|                     | WO95/06030         | 3/2/95   | PCT     |       |          |             |    |
|                     | WO95/07269         | 3/16/95  | PCT     |       |          |             |    |
|                     | WO95/09843         | 4/13/95  | PCT     |       |          |             |    |
|                     | WO95/14016         | 5/26/95  | PCT     |       |          |             |    |
|                     | WO95/32185         | 11/30/95 | PCT     |       |          |             |    |
|                     | WO96/33187         | 10/24/96 | PCT     |       |          |             |    |
|                     |                    |          |         |       |          |             |    |
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